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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,650	08/11/2000	Chao-Feng Zheng	25436/1510	7825

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PALMER & DODGE, LLP  
KATHLEEN M. WILLIAMS / STR  
111 HUNTINGTON AVENUE  
BOSTON, MA 02199

EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/637,650

Applicant(s)

ZHENG, CHAO-FENG

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 10-23 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 24-26, 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

Claims 10-23 and 27-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

This application contains claims 10-23 and 27-32 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively

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beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 27-32 have been renumbered 33-38.

***Claim Rejections - 35 USC § 103***

Claims 1-9, 24-26, and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montminy (U.S. Patent No. 6,063,583) in view of Gilman et al (U.S. Patent No. 6,306,649), for reasons of record set forth in Paper No. 8, mailed 7/2/02 (which is extended to new claims 33-38 as necessitated by the applicant's amendment filed 12/19/02). Applicants' arguments filed 12/19/02 have been fully considered but they are not deemed to be persuasive.

***Response to Arguments***

The applicant argues that Montminy teaches the use of three constructs and the present invention discloses cell lines and kits which use two constructs. This argument is not persuasive for the following reasons.

The claimed cell lines and kits comprising the cell lines are claimed as "A cell line comprising a stably integrated recombinant nucleic acid construct comprising". The use of "comprising" indicates that the cell lines can contain anything

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else in addition to the two recited parts of the construct. Montminy does teach cell lines that have the two recited components: a reporter gene operably linked to a recognition sequence for a sequence-specific DNA-binding protein (Gal4) and a nucleic acid construct comprising a promoter operatively linked to a nucleic acid encoding a fusion protein comprising a sequence-specific DNA binding domain (Gal4), wherein the DNA binding domain specifically binds said recognition sequence and a conditionally active transactivation domain (the Gal4 DNA binding domain is taught as being operatively linked to CREB (specifically, column 7, lines 5-7)) (which, because it comprises the whole CREB protein, comprises the conditionally active transcriptional domain of CREB, which is conditionally active with respect to both phosphorylation and protein:protein interaction). The binding of the fusion protein to the Gal4 response element results in transactivation of the reporter gene (when, of course, the conditionally active transactivation domain of CREB is activated, by either phosphorylation or protein:protein binding). Thus, Montminy does teach the same components of the cells and kits as recited in the claims, making obvious the claimed invention (in combination with the Gilman et al reference). The applicant's argument is only drawn to the deficiencies of Montminy, addressed above, and not drawn

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to the obviousness of the combination of references or the teachings of Gilman et al that are relied upon for the rejection.

The applicant also argues that Montminy teaches that the GAL4 response element activates the reporter gene, while the present claims recite that the transactivation domain of CREB activates the reporter gene, and therefore Montminy teaches upstream or cis-activation, while the present claims specifically recite transactivation from the other construct. This argument is not persuasive because what the applicant asserts are two different ways of activation, are actually the two parts of the same process, as claimed. It is the binding of the fusion protein comprising the transactivation domain of CREB to the Gal4 recognition sequence (due to the Gal4 DNA binding domain that is the other half of the fusion protein) which brings the transactivation domain into the proximity of the reporter gene (which then, by transactivation, recruits the other components of the transcriptional apparatus so that the structural gene operatively linked to the Gal4 recognition sequence (the reporter gene) is transcribed. Thus, the activation of transcription comprises the cis activation accomplished by the Gal4 recognition sequence and the

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transactivation of the fusion protein comprising the  
transactivation domain (when that domain is activated).

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 33-38 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 25-26. This is a new objection necessitated by the applicant's amendment to the claims filed 12/19/02. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 33-38 are drawn to kits that have different intended uses from claims 25-26 and from each other, but the intended use

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(for performing a method ...) in each case does not impart any structural difference upon the claimed kit, so each claimed kit is identical in structure to the kit of claim 25 or claim 26, which kits are drawn to comprising a cell line comprising a stably integrated recombinant nucleic acid construct comprising a reporter gene operably linked to a recognition sequence for a sequence-specific DNA binding protein; and a stably integrated recombinant nucleic acid construct comprising a sequence encoding a fusion protein (of a specific structure) (claim 25) and further comprising a nucleic acid expression construct encoding an upstream activator of the conditionally active transactivation domain (claim 26). Because the kits encompass the same scope due to having the same structural limitations, they are duplicates of each other.

Claim 1-9, 24-26, and 33-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 24-32 (extended to new claims 27-32 as necessitated by the Applicant's amendment in that application, filed 12/19/02) of copending Application No. 09/637,511, for reasons of record set forth in Paper No. 8, mailed 7/2/02 (which is extended to new claims 33-38 as necessitated by the applicant's amendment filed 12/19/02).



***Response to Arguments***

The applicant has indicated that upon indication of allowable subject matter, Applicant will provide the appropriate Terminal Disclaimer. This is acceptable, but the rejection remains of record until the acceptable TD is filed.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014.

NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

March 6, 2003